

PATENT

ATTORNEY DOCKET NO. CGNE.099.04US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Knauf and Kridl) Examiner: Not Yet Assigned
Serial No.: Not Yet Assigned) Art Unit: Not Yet Assigned
Filed: February 9, 2001)
For: **METHODS AND COMPOSITIONS**) **PRELIMINARY AMENDMENT**
FOR REGULATED TRANSCRIPTION)
AND EXPRESSION OF)
HETEROLOGOUS GENES)

Assistant Commissioner of Patents
Washington, D.C. 20231

Sir:

This is submitted with the above-referenced application as a preliminary amendment.
The Examiner is respectfully requested to make the following amendments.

AMENDMENTS

IN THE SPECIFICATION

On page 1, line 6, after "This application is a", insert --continuation of U.S.S.N. 09/232,861, filed January 15, 1999, which is a continuation of U.S.S.N 08/812,665, filed March 7, 1997, now U.S. Patent No. 5,981,839, which is a--.

On page 1, line 7, after "June 7, 1995," insert --now U.S. Patent No. 5,750,385,--.

On page 1, line 8, change "pending" to --now U.S. Patent No. 5,753,475,--.

CERTIFICATE OF EXPRESS MAILING

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(Signature)

Francis Guerra

(Printed Name)

Application Elements:

87 Pages of Specification, Claims and Abstract

40 Sheets of formal drawings

☒ Declaration

☐ Unexecuted Combined Inventor Declaration and Power of Attorney

☒ Copy from prior application (37 CFR 1.63(d) for a continuation or divisional).

The entire disclosure of the prior application from which a copy of the declaration is herein supplied is considered as being part of the disclosure of the accompanying continuation application and is hereby incorporated by reference therein.

☒ Executed Revocation and Appointment of New Power of Attorney (copy from priority application serial no. 08/812,665)

☐ Deletion of inventors Signed statement attached deleting inventor(s) named in the prior application, *see* CFR 1.63(d)(2) and 1.33(b).

☒ Copy of Notice of Recordation of Assignment for priority application no. 08/812,665

Accompanying Application Parts:

☐ Assignment and Assignment Recordation Cover Sheet (recording fee of \$40.00 enclosed)

☐ Power of Attorney

☐ 37 CFR 3.73(b) Statement by Assignee

☒ Information Disclosure Statement with Form 1449

☐ Copies of IDS Citations

☒ Preliminary Amendment

☒ Return Receipt Postcard

- ☐ Small Entity Statement(s) ☐ Statement filed in prior application.
Status still proper and desired.
- ☐ Other:
- ☐ A sequence listing.
- ☐ paper copy.
- ☐ Request to use computer readable copy from parent application.
- ☐ Statement in Compliance with Requirements for Patent Applications Containing Nucleotide and/or Amino Acid Sequence.

Claim For Foreign Priority

- ☐ Priority of _____ Application No. _____ filed on _____
is claimed under 35 U.S.C. § 119
- ☐ The certified copy has been filed in prior application U.S. Application No. _____
- ☐ the certified copy will follow.

Extension of Time for Prior Pending Application

- ☐ A Petition for Extension of Time is being concurrently filed in the prior pending application. A copy of the Petition for Extension of Time is attached.

Amendments

- ☒ See Preliminary Amendment
- ☐ Amend the specification by inserting before the first line the sentence: "This is a ☒ Continuation ☐ Continuation-in-part ☐ Nonprovisional application of copending prior
- ☐ Application Serial No. _____ filed on _____.
- ☐ International Application _____ filed on _____, which designated the United States, disclosure of which is incorporated herein by reference."
- ☐ Cancel in this application original claims _____ of the prior application before calculating the filing fee

Knauf and Kridl

Attorney Docket No. CGNE.099.04US

On page 1, line 10, change "07/267,865" to --07/267,685--.

On page 18, line 18, change "vestors" (both occurrences) to --vectors--.

On page 21, line 11, change "monocatoledenous" to --monocotyledenous--.

On page 21, line 18, change " 10_8 " to -- 10^8 --.

On page 28, lines 9-10, change "12301 Parklawn Drive, Rockville, Maryland, 20852" to --10801 University Blvd., Manassas, VA 20110--.

On page 30, line 25, change " ^{32}p " to -- ^{32}P --.

On page 30, line 26, change "amioglycoside" to --aminoglycoside--.

On page 31, line 5, change "lanamycin" to --kanamycin--.

On page 31, line 7, change "(1984)____:_____" to --(1985) 4(1):25-32)--.

On page 31, line 13, change "1.1kd" to --1.1kb--.

On page 32, lines 4 and 7, change "1.OkB" to --1.0kb--.

On page 38, line 8, change "eas" to --ease--.

On page 58, lines 19, 23 and 32, change "PCGN" to --pCGN--.

On page 59, line 15, change "MRNA" to --mRNA--.

On page 65, lines 7 and 23, change " ^{32}p " to -- ^{32}P --.

On page 65, line 11, change "toot" to --root--.

On page 67, line 9, change " ^{32}p " to -- ^{32}P --.

On page 74, line 12, change "S*ac*I" to --S*ac*I--.

On page 75, lines 26 and 27, change "X*ho*I" to --X*ho*I--.

IN THE CLAIMS:

Cancel Claims 1-16

17. (Amended) A method for obtaining a plant which produces at least one seed having a modified phenotype, said method comprising:

transforming a host plant cell with a DNA construct under genomic integration conditions, wherein said construct comprises as operably linked components in the direction of

transcription, a promoter region obtainable from a gene, wherein transcription of said gene is preferentially regulated in plant seed tissue, a DNA sequence of interest other than the native coding sequence of said gene, and a transcription termination region, wherein said components are functional in a plant cell,

whereby said DNA construct becomes integrated into a genome of said plant cell,
regenerating a plant from said transformed plant cell, and
growing said plant under conditions whereby said DNA sequence of interest is expressed and a seed having said modified phenotype is obtained.

18. (Amended) A method of altering the phenotype of plant seed tissue as distinct from other plant tissue, said method comprising:

growing a plant which produces at least one seed, wherein said plant comprises cells containing a DNA construct integrated into their genome, said DNA construct comprising, in the 5' to 3' direction of transcription, a transcriptional initiation region from a gene, wherein transcription of said gene is preferentially regulated in a plant seed tissue, a DNA sequence of interest other than the coding sequence native to said transcriptional initiation region, and a transcriptional termination region, whereby transcription of said DNA sequence of interest is [transcribed under transcriptional control of] controlled by said transcriptional initiation region and plant seed tissue having an altered phenotype is obtained.

19. (Reiterated) The method according to Claim 17 or 18, wherein said DNA construct is flanked by T-DNA.

20. (Amended) The method according to Claim 19, wherein said plant is [a] selected from the group consisting of soybean, [or] rapeseed [plant] and tomato.

21. (Reiterated) The method according to Claim 17 or 18 wherein said DNA sequence of interest encodes an enzyme.

22. (Reiterated) The method according to Claim 17 or 18 wherein said DNA sequence of interest is an antisense sequence.

23. (Amended) [The] A method [according to Claim 17 or 18] for obtaining a plant which produces at least one seed having a modified phenotype, said method comprising:
transforming a host plant cell with a DNA construct under genomic integration conditions, wherein said construct comprises as operably linked components in the direction of transcription, a promoter region obtainable from a gene, wherein said gene is preferentially transcribed during seed embryogenesis, a DNA sequence of interest other than the native coding sequence of said gene, and a transcription termination region, wherein said components are functional in a plant cell,
whereby said DNA construct becomes integrated into a genome of said plant cell,
regenerating a plant from said transformed plant cell, and
growing said plant under conditions whereby said DNA sequence of interest is expressed and a plant having said seed with a modified phenotype is obtained.

24. (Amended) The method according to Claim 23 or 52, wherein said gene is transcribed from about day 7 to day 40 postanthesis.

25. (Reiterated) The method according to Claim 17 or 18 wherein said gene is transcribed during seed maturation.

26. (Reiterated) The method according to Claim 25 wherein said gene is transcribed from about day 11 to day 30 postanthesis.

27. (Reiterated) The method according to Claim 18, wherein said transcriptional initiation region further comprises a translational initiation region and said DNA sequence of interest is an open reading frame encoding an amino acid sequence.

28. (Amended) A method for modifying a genotype of a plant to impart a desired characteristic to seed as distinct from other plant tissue, said method comprising:

transforming under genomic integration conditions, a host plant cell with a DNA construct comprising in the 5' to 3' direction of transcription, a transcriptional initiation region from a gene, wherein transcription of said gene is preferentially regulated in a plant seed tissue, a DNA sequence of interest other than the native coding sequence of said gene, and a transcriptional termination region, whereby said DNA construct becomes integrated into the genome of said plant cell;

regenerating a plant from said transformed host cell; and

growing said plant to produce seed under conditions whereby said DNA sequence of interest is expressed and a plant having a modified genotype is obtained.

29. (Reiterated) The method according to Claim 28, wherein said DNA construct is flanked by T-DNA.

30. (Reiterated) The method according to Claim 28, wherein said plant is a *Brassica* plant.

31. (Reiterated) The method according to Claim 28, wherein said DNA sequence of interest encodes an enzyme.

32. (Reiterated) The method according to Claim 28, wherein said DNA sequence of interest is an antisense sequence.

33. (Amended) The method according to Claim 28, wherein said plant is a soybean or a tomato plant.

34. (Amended) A method for modifying transcription in seed tissue as distinct from other plant tissue, said method comprising:

growing a plant capable of developing seed tissue under conditions to produce seed, wherein said plant comprises cells containing a DNA construct integrated into their genome, said DNA construct comprising, in the 5' to 3' direction of transcription, a seed-specific transcriptional initiation region, a DNA sequence of interest other than the coding sequence native to said transcriptional initiation region, and a transcriptional termination region, whereby transcription of said DNA sequence of interest is [transcribed under the transcriptional control of] controlled by said seed-specific transcriptional initiation region.

35. (Reiterated) The method according to Claim 34, wherein said DNA sequence of interest is an antisense sequence.

36. (Reiterated) The method according to Claim 34, wherein said plant is of the genus *Brassica*.

37. (Reiterated) The method according to Claim 34, wherein said transcriptional initiation region further comprises a translational initiation region and said DNA sequence of interest is an open reading frame encoding an amino acid sequence.

38. (Amended) The method according to Claim 34, wherein said plant is a soybean or a tomato plant.

39. (Amended) A method to selectively express a heterologous DNA sequence of interest in seed tissue as distinct from other plant tissue, said method comprising:

growing a plant capable of developing a seed tissue under conditions to produce seed, wherein said plant comprises cells having a genomically integrated DNA construct comprising, as operably linked components in the 5' to 3' direction of transcription, a seed-specific transcriptional initiation region and a translational initiation region, a DNA sequence of interest other than the coding sequence native to said transcriptional initiation region, and a transcriptional termination region downstream of said DNA sequence of interest, whereby said DNA sequence of interest is expressed under control of said seed-specific transcriptional and translational initiation region.

40. (Reiterated) The method according to Claim 39, wherein said plant is of the genus *Brassica*.

41. (Amended) The method according to Claim 39, wherein said plant is a soybean or a tomato plant.

Please add the following new claims:

42. (New) The method according to Claim 17 or Claim 18, wherein said DNA sequence of interest is a structural gene.

43. (New) The method according to Claim 17 or Claim 18, wherein said DNA sequence of interest is an open reading frame encoding an amino acid sequence.

44. (New) The method according to Claim 17 or Claim 18, wherein said transcriptional initiation region further comprises a translational initiation region.

45. (New) A method for modifying transcription in plant seed tissue as distinct from other plant tissue, said method comprising:

growing a plant wherein said plant comprises cells containing a DNA construct integrated into their genome, said construct comprising:

a transcriptional initiation region from a gene wherein said gene is preferentially expressed in plant seed tissue, a DNA sequence of interest other than the coding sequence native to said transcriptional initiation region, wherein said DNA sequence of interest is controlled by said transcriptional initiation region, whereby transcription in said plant seed tissue is modified as distinct from other plant tissue.

46. (New) The method according to Claim 45, wherein said DNA construct further comprises a translational initiation region and a termination region.

47. (New) A method to selectively express a heterologous DNA sequence of interest in plant seed tissue as distinct from other plant tissue, said method comprising:
growing a plant wherein said plant comprises cells containing a DNA construct integrated into their genome, said construct comprising as operably linked components in the direction of transcription, a promoter region from a gene that is preferentially expressed in plant seed tissue and a DNA sequence of interest, wherein said DNA sequence of interest is other than the coding sequence native to said promoter region and is expressed under the control of said promoter region whereby said DNA sequence of interest is expressed in plant seed tissue.

48. (New) The method according to Claim 17 or Claim 18, wherein said gene is a cruciferin gene.

49. (New) The method according to Claim 48, wherein said promoter region or said transcriptional region is obtained from the 5' untranslated region associated with the coding region of said cruciferin gene.

50. (New) The method according to Claim 17, wherein said promoter region is from a gene encoding a storage protein.

51. (New) A method according to Claim 18, wherein said transcriptional initiation region is from a gene encoding a storage protein.

52. (New) A method of altering the phenotype of plant seed tissue as distinct from other plant tissue, said method comprising:

growing a plant, wherein said plant comprises cells containing a DNA construct integrated into their genome, said DNA construct comprising, in the 5' to 3' direction of transcription, a transcriptional initiation region from a gene, wherein said gene is preferentially transcribed during seed embryogenesis, a DNA sequence of interest other than the coding sequence native to said transcriptional initiation region, and a transcriptional termination region, whereby transcription of said DNA sequence of interest is controlled by said transcriptional initiation region and plant seed tissue having an altered phenotype is obtained.

53. (New) A method for obtaining a plant which produces at least one seed having a modified phenotype, said method comprising:

transforming a host plant cell with a DNA construct under genomic integration conditions, wherein said construct comprises as operably linked components in the direction of transcription, a promoter region obtainable from a gene encoding a seed storage protein, wherein transcription of said gene is preferentially regulated in plant seed tissue, a DNA sequence of interest other than the native coding sequence of said gene, and a transcription termination region, wherein said components are functional in a plant cell,

whereby said DNA construct becomes integrated into a genome of said plant cell, regenerating a plant from said transformed plant cell, and

growing said plant under conditions whereby said DNA sequence of interest is expressed and a plant having said seed with a modified phenotype is obtained.

54. (New) A method of altering the phenotype of plant seed tissue as distinct from other plant tissue, said method comprising:

growing a plant, wherein said plant comprises cells containing a DNA construct integrated into their genome, said DNA construct comprising, in the 5' to 3' direction of transcription, a transcriptional initiation region from a gene encoding a seed storage protein, wherein transcription of said gene is preferentially regulated in a plant seed tissue, a DNA sequence of interest other than the coding sequence native to said transcriptional initiation region, and a transcriptional termination region, whereby transcription of said DNA sequence of interest is controlled by said transcriptional initiation region and plant seed tissue having an altered phenotype is obtained.

REMARKS

Amendments to page 1 of the specification were made to correct the priority claim for the present application and to reflect that application serial no. 08/812,665 has issued as USPN 5,981,839; application serial no. 08/484,941 has issued as USPN 5,750,385 and application serial no. 08/105,852 has issued as USPN 5,753,475, and to correctly recite application serial no. 07/267,685. The filing receipt to application serial no. 07/267,685 is attached.

Minor amendments were made to pages 18, 21, 28, 30, 31, 32, 38, 58, 59, 65, 67, 74 and 75 of the specification to correct typographical errors.

Applicants have amended Claims 17, 18, 20, 23, 24, 28, 33, 34, 38, 39 and 41, and added new claims 42-54.

Claims 17, 18 and 28 have been amended to recite a plant "which produces at least one seed", and a gene which is "preferentially" regulated in plant seed tissue. Support is found on page 9, lines 1-11, page 15, lines 14-18 and on page 51, lines 12-15.

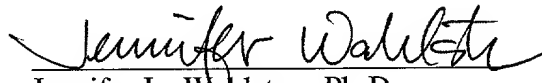
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CONCLUSION

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned at (650) 328-4400.

Respectfully submitted,

Dated: 6 February, 2001


Jennifer L. Wahlsten, Ph.D.
Reg. No. 46,226

Rae-Venter Law Group, P.C.
P. O. Box 60039
Palo Alto, CA 94306
Telephone: (650) 328-4400
Facsimile: (650) 328-4477

BRV/JLW
Enclosures

Claims 20, 33, 38 and 41 were amended to recite "tomato plant". Support is found on page 22, line 24.

Claim 23 was amended to be an independent claim incorporating the language of Claim 17.

Claim 24 was amended to depend from both Claims 23 and 52.

Claim 34 was amended for clarity.

Claim 39 was amended to correct a typographical error.

Support for new Claim 42 is found on page 17, lines 1-20.

Support for new Claims 43, 44 and 46 is found in original Claim 27.

Support for new Claim 45 is found in original Claims 18 and 34.

Support for new Claim 47 is found in original Claims 17, 18 and 39.

Support for new Claim 48 is found on page 62, line 30 through page 63, line 2.

Support for new Claim 49 is found on page 13, lines 14-18.

Support for new Claims 50-51 is found on page 14, lines 23-24 and page 15, lines 14-16.

New Claim 52 is originally submitted Claim 23 made independent and incorporating the language of Claim 18. Support is also found on page 9, lines 1-11, page 15, lines 14-18 and on page 51, lines 12-15.

Support for new Claims 53 and 54 is found on page 6, lines 15-16.

Applicants believe that no new matter has been added by any of these amendments and therefore respectfully request the Examiner to enter them.